REMARKS

Applicants have amended claim 31 to recite:

31. Method for determining expression of a MAGE-C3 gene in a sample, comprising contacting said sample with (i) an ~~oligonucleotide having a sequence set forth by~~ oligonucleotide fragment of SEQ ID NO: 21 comprising a sequence of nucleotides 175-195 of SEQ ID NO: 21 and (ii) an oligonucleotide ~~having a sequence~~ that is fully complementary to a fragment of SEQ ID NO: 21 comprising nucleotides 711-731 of SEQ ID NO: 21, under conditions favoring hybridization of the sequences of (i) or (ii) to an MAGE-C3 coding sequence, carrying out polymerase chain reaction and determining expression product to determine presence of an MAGE-C3 coding sequence in said sample.

Support for the amendments is found on page 11, lines 19 to 22, which recites:

> "MAGE-C1 specific, MAGE-C2 specific, MAGE-C3 specific, MAGE-B5 specific and MAGE-B6 specific oligonucleotides derived respectively from SEQ ID NO: 9, 18, 21, 23 or 25 may be useful in kits for PCR assays to amplify and thus detect MAGE-C3, MAGE-B5 and MAGE-B6 nucleic acid molecules in a sample."

Claim 31 stands rejected under 35 U.S.C. 112, first paragraph for purported lack of written description and for purported lack of enablement. In particular, the Examiner contends that the term "having" is open ended and thus has the same meaning as "comprising." As such the Examiner contends that the language encompasses numerous structural variants that are not described in the application. The Examiner contends that the specification does not provide the complete structure of any oligonucleotide primer other than the oligonucleotide consisting of nucleotides 175-195 of SEQ ID NO: 21 and an oligo that is a full length complement of an oligo consisting of nucleotides 711-731 of SEQ ID NO: 21.

The Examiner also contends that the specification is only enabling of a method for determining expression of MAGE-C3 that uses oligonucleotides consisting of nucleotides 175-195 of SEQ ID NO: 21 and an oligonucleotide that is the full complement of nucleotides 711-731 of SEQ ID NO: 21 and that uses specific conditions for a PCR reaction. Applicants

respectfully disagree and in view of the amendments to the claims and the following remarks Applicant respectfully request that the Examiner reconsider and withdraw the rejection of the claim.

As amended claim 31 recites:

31. Method for determining expression of a MAGE-C3 gene in a sample, comprising contacting said sample with (i) an ~~oligonucleotide having a sequence set forth by~~ oligonucleotide fragment of SEQ ID NO: 21 comprising a sequence of nucleotides 175-195 of SEQ ID NO: 21 and (ii) an oligonucleotide ~~having a sequence~~ that is fully complementary to a fragment of SEQ ID NO: 21 comprising nucleotides 711-731 of SEQ ID NO: 21, under conditions favoring hybridization of the sequences of (i) or (ii) to an MAGE-C3 coding sequence, carrying out polymerase chain reaction and determining expression product to determine presence of an MAGE-C3 coding sequence in said sample.

Applicants have provided the entire sequence of SEQ ID NO: 21 and have disclosed that oligonucleotides derived from SEQ ID NO: 21 may be used on PCR to amplify and detect MAGE-C3 in a sample. See, e.g., page 11, lines 19-22 which recites:

> "MAGE-C1 specific, MAGE-C2 specific, MAGE-C3 specific, MAGE-B5 specific and MAGE-B6 specific oligonucleotides derived respectively from SEQ ID NO: 9, 18, 21, 23 or 25 may be useful in kits for PCR assays to amplify and thus detect MAGE-C3, MAGE-B5 and MAGE-B6 nucleic acid molecules in a sample."

Furthermore, it is well within the ability of one of ordinary skill in the art to prepare fragments of SEQ ID NO: 21 that would encompass nucleotides 175-195. In addition, one of skill in the art could readily generate oligonucleotides that are fully complementary to fragments of SEQ ID NO: 21 comprising nucleotides 711-731.

The Examiner contends that the claims must recite particular PCR conditions because otherwise, in the Examiner's opinion, the method would detect unrelated sequences. The Examiner contends that the unrelated sequences would be detected even if the primers consisted

of particular sequences. The Examiner further contends that the term "hybridization" encompasses any hybridization condition, from low to high stringency conditions. Applicants respectfully disagree with the Examiner's evaluation of the claim.

Terms recited in the claims must be interpreted within the context of the invention. In claim 31 Applicants specifically use the term "hybridization" in the context of a polymerase chain reaction,

> "...under conditions favoring hybridization of the sequences of (i) or (ii) to a MAGE-C3 coding sequence, carrying out polymerase chain reaction and determining expression product to determine presence of an MAGE-C3 coding sequence in said sample"

Applicant's claimed method is also one for detecting MAGE-C3 in a sample. The conditions as recited in the claim favor hybridization of the recited oligonucleotides to a MAGE-C3 coding sequence. It would be nonsensical for one of skill in the art seeking to detect a MAGE-C3 coding sequence in a sample to use conditions that would not favor hybridization of the oligonucleotides to the MAGE-C3 sequences so that unrelated sequence would be detected, obscuring the detection of MAGE-C3. PCR is a technique well known and routinely used by those of skill in the art. Thus one of ordinary skill in the art would need no more instruction than that provided by applicants to practice the invention.

Furthermore, the Examiner has evaluated the term "hybridization" in isolation and not within the context of any particular method. The Examiner states

> "As conventionally understood in the art and as taught by US Patent No. 5,912,143, hybridization is used to refer to any process by which a strand of nucleic acid binds with a complementarty strand through base pairing (col. 5, lines 3-5) and further teaches that numerous equivalent conditions may be employed to comprise either low or high stirngency conditions and hybridization solutions by be varied to generate conditions of either low or high stringency. (col. 5, lines 57-67)"

But, the Examiner has failed to cite any particular passages in the '143 Patent that place the term "hybridization" in any context, much less in the context of a PCR reaction for use in detecting particular sequences in a sample.

The Examiner cites Sambrook *et al.*, eds, 1989, 2nd Ed, Molecular Cloning, A Laboratory Manual, Cold Spring Harbor Laboratory Press, Cold Spring Harbor p.11.52 (Sambrook) in the Office Acition (page 10). The section of Sambrook cited by the Examiner relates to hybridization of "guessmers" in Northern and Southern hybridizations to screen libraries and not to the particular oligonucleotides as they are recited in the amended claims or to their use in PCR reactions. Nonetheless, Sambrook teaches how to determine conditions that favor hybridization to "correct" sequences and thus demonstrates that one of skill in the art could readily devise conditions that would favor such "correct" hybridization. If anything, Sambrook supports the enablement of Applicants' claim.

The application provides an example of PCR conditions that are useful for amplifying MAGE-C3. One of skill in the art, in view of the teachings of this application and what is well known in the art, could easily determine appropriate PCR conditions that would favor hybridization of a particular fragment of SEQ ID NO: 21, or the complement thereof, to a MAGE-C3 coding sequence.

The foregoing remarks demonstrate that Applicants have fully described and enabled the method as recited in the claim by instructing those of skill in the art to use the oligonucleotides recited therein and to practice the claimed method "under conditions favoring hybridization of the sequences of (i) or (ii) to a MAGE-C3 coding sequence, carrying out polymerase chain reaction and determining expression product to determine presence of an MAGE-C3 coding sequence in said sample."

In view of the above, the presently pending claim in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. LUD 5611.2 DIV from which the undersigned is authorized to draw.

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Respectfully submitted,

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